

**REMARKS**

Claims 71 and 72 are pending in the subject application.

**I. Written Description Rejection.**

Claims 71 and 72 are rejected under 35 U.S.C. sec. 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses the rejection.

**A.       The subject application necessarily shows that exemplified cells are not genetically modified to express heparanase.**

The Examiner states in the final Action that “while it is appreciated that applicants do describe species and examples of encompassed biological preparations that are not **necessarily** genetically modified cells, applicants do not have support for the negative limitation that none of said cells is **genetically modified**.”

In making this statement, a critical error is being made in reading the claims. Specifically, claim 71 as currently amended does **not** recite that none of said cells is genetically modified. Rather, the claim recites that none of said cells is genetically modified **to express heparanase**.

The examples in the subject application describe a cell preparation to which heparanase **is added**. See, for example, Application at pages 48, lines 18-22, which describes **adding** heparanase to a preparation of bone marrow stromal cells. In view of this disclosure, the skilled artisan reading the application would **necessarily** know that such exemplified cells have **not** been genetically modified to express heparanase. **If they were so modified, there would be no need to add heparanase.** The skilled artisan would clearly understand this.

**B. To satisfy the written description requirement, disclosure can be implicit or inherent.**

The MPEP provides that the disclosure to support a claim can be **implicit or inherent**. MPEP sec. 2163(I)(B). Moreover, the **Examiner** has the **burden** of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. Sec. 2163(II)(A).

Reading the subject application, the skilled artisan would clearly know that it implicitly describes cells that are not genetically modified to express heparanase. Therefore, claim 71 is adequately supported by the written description of the application. Furthermore, the Examiner has not provided reasoning or an explanation why this implicit disclosure is not sufficient and, therefore, has not met his burden.

Accordingly, Applicant respectfully requests that this rejection be withdrawn. Should this rejection not be withdrawn, Applicant respectfully requests that the Examiner meet his required burden and provide an explanation why the implicit disclosure in the subject application is not sufficient for fulfilling the written description requirement of pending claims 71 and 72.

## II. Indefiniteness rejection

Claim 72 is rejected under 35 U.S.C. sec. 112, second paragraph, as allegedly indefinite. Specifically, it is alleged that the recitation in claim 72 that cells can be “genetically modified” is unclear given that claim 71 now recites that none of the cells are genetically modified. Applicant respectfully traverses the rejection.

As discussed above, claim 71 as currently amended does **not** recite that none of said cells is genetically modified. Rather, the claim recites that none of said cells is genetically modified **to express heparanase**. In light of this critical point, Applicant respectfully submits that there is no issue of indefiniteness whatsoever.

Claim 71 merely recites that the cells are not genetically modified to express heparanase. Claim 72 recites that the cells can be genetically modified. Thus, it is absolutely clear that the cells of claim 72 can be genetically modified, **except** for a genetic modification for expressing heparanase. There is simply no other way to read

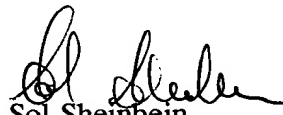
claim 72. If the Examiner sees another way of reading the claim, he is invited to share it with Applicant.

In view of the clear reading of the claims, Applicant respectfully requests that this rejection be withdrawn.

### CONCLUSION

All of the issues raised in the final Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore, Applicant respectfully requests a Notice of Allowance to this effect.

Respectfully submitted,



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